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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,463	12/03/2003	Richard Hayes	AQMED.0101	5879

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EXAMINER	
CORRIGAN, JAIME W	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,463	HAYES ET AL.	
	Examiner	Art Unit	
	Jaime W. Corrigan	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-58 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11-8-04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 9-10, 13, 15-21, 23, 25-28, 30-31, 34-38, 40, 42, 46-50, 52, 55, 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Bene et al. (PN 5,698,090).

Regarding claims 1, 25, 42 Bene et al. discloses a first pump (See Figure 1 (12)) that is configurable to pump a first metered (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-8) amount of a first fluid through a first delivery line (See Figure 1 (11)) to a catheter (See Figure 1 (Between (8) and (9))); a second (See Figure 1 (22)) pump that is configurable to pump a second metered (See Column 3 Lines 57-67, Column 4 Lines 1-67, Column 5 Lines 1-17) amount of a second fluid through a second delivery line (See Figure 1 (21)), separate from said first delivery line, to said catheter (See Figure 1 (Between (8) and (9))); a processor (See Figure 1 (25)), connected to control said first and said second pumps such that said second metered amount has a definable relationship to said first metered amount (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-17); wherein the lumen of said first delivery line and the lumen of said second delivery line remain

separate up to a connection point (See Figure 1 (8)) of said first and second delivery lines to said catheter.

Regarding claim 2 Bene et al. discloses the first fluid is an oxygen-carrying solution (See Figure 1 (10), Column 3 Lines 34-39).

Regarding claim 3 Bene et al. discloses the first fluid is blood (See Figure 1 (10), Column 3 Lines 34-39) .

Regarding claim 4 Bene et al. discloses first fluid comprises blood from the patient (See Figure 1 (6), (7)).

Regarding claim 6 Bene et al. discloses a plurality (See Figure 1 (6), (19)) of additional pumps pumping respective (See Column 3 Lines 34-44, Column 4 Lines 14-48) fluids under the control of said processor (See Figure 1 (25)).

Regarding claims 7, 55 Bene et al. discloses first pump (See Figure 1 (12)) is further configurable to combine a third metered amount of a third fluid with the first fluid and to pump both the first and the third fluids into said first delivery line (See Column 3 Lines 34-67, Column 4 Lines 1-67, Column 5 Lines 1-8).

Regarding claim 9 Bene et al. discloses said processor (See Figure 1 (25))

receives feedback from monitors (See Figure 1 (23), (24), Column 3 Lines 57-67, Column 4 Lines 1-13) and can automatically alter operational parameters to meet predefined objectives.

Regarding claims 10, 57 Bene et al. discloses an operator can alter the definable relationship between said first metered amount and said second metered amount (See Column 6 Lines 33-67).

Regarding claim 13 Bene et al. discloses a monitor (See Figure 1 (25)) to detect one or more conditions, the conditions including the rate of flow (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8), the temperature, the pressure, and the concentration of a fluid within said pumping system.

Regarding claims 15, 34, 46 Bene et al. discloses said processor (See Figure 1 (25)) is connected to control the activity of a portion (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8) of said clinical fluid pumping system.

Regarding claims 16, 35, 47 Bene et al. discloses said processor is connected to control the operation of a valve (See Figure 1 (15), (16)).

Regarding claims 17, 36, 48 Bene et al. discloses said processor is

connected to control (See Column 3 Lines 57-67, Column 4 Lines 1-13, 59-67, Column 5 Lines 1-8) the speed of said first pump .

Regarding claims 18, 37, 49 Bene et al. discloses said processor (See Figure 1 (25)) is connected to receive inputs from a monitor (See Figure 1 (23), (24)) and to send signals to control a portion of said clinical fluid pumping system.

Regarding claims 19, 38, 50 Bene et al. discloses a display and control panel (See Figure 1 (25)) connected to provide information regarding the operation of said pumping system to a user and to accept input from the user (See Column 4 Lines 59-63, Column 6 Lines 33-67).

Regarding claim 20 Bene et al. discloses said first (See Figure 1 (11)) delivery line and said second delivery (See Figure 1 (21)) line are separate lumen within a single tubing (See Figure 1 (8)).

Regarding claims 21, 40 Bene et al. discloses said first delivery line (See Figure 1 (11)) and said second (See Figure 1 (21)) delivery line are separate pieces of tubing.

Regarding claims 23, 52 Bene et al. discloses said catheter (See Figure 1 (9)) is directly inserted into a circulatory vessel serving a target organ and has a single lumen.

Regarding claim 26 Bene et al. discloses said pumping means consists of a first (See Figure 1 (12)) pump.

Regarding claim 27 Bene et al. discloses said pumping means comprises a first (See Figure 1 (12)) pump and a second (See Figure 2 (22)) pump.

Regarding claim 28 Bene et al. discloses the co-mingling of the first fluid and the second fluid is delayed (See Figure 1 (11), (21)) to prevent degradation of the second fluid.

Regarding claim 30 Bene et al. discloses means (See Figure 1 (25)) to control (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8) the fluid flow rate.

Regarding claim 31 Bene et al. discloses a means to control (See Column 3 Lines 24-67, Column 4 Lines 1-67, Column 5 Lines 1-8) the known relationship between the first and the second fluids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5, 39, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090) in view of Gilles et al. (PN 6,272,370).

Bene et al. discloses the invention as recited in claims 1, 25, 42 however, fails to disclose said receiving step receives a fluid comprising blood and said pumping step pumps adenosine.

Gilles et al. teaches that it is conventional in the art to utilize said receiving step receives a fluid comprising blood (See Column 23 Lines 51-60) and said pumping step pumps adenosine (See Column 23 Lines 51-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized said steps receiving blood and pumping adenosine taught by Gilles et al. in the Bene et al. device since it would improve catheter-based administration of medicine.

Claims 8, 12, 29, 32, 43-44, 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090) in view of Hogard et al. (PN 6,284,131).

Bene et al. discloses the invention as recited in claims 1, 25, 42 however, fails to disclose the fluids are delivered at a controlled temperature and pressure; comprising a

temperature controller, configurable to provide heating or cooling to fluids in at least one of said first delivery tube and said second delivery line without contaminating the fluids; passing at least one of the fluids through a heat exchanger, whereby the at least one of the fluids is brought to a desired temperature prior to delivery to said catheter.

Hogard et al. teaches that it is conventional in the art to utilize the fluids are delivered at a controlled temperature and pressure (See Column 2 Lines 1-15, Column 4 Lines 25-36); comprising a temperature controller, configurable to provide heating or cooling to fluids in at least one of said first delivery tube and said second delivery line without contaminating the fluids (See Column 2 Lines 1-15, Column 4 Lines 25-36); passing at least one of the fluids through a heat exchanger (See Figure 1A (16)), whereby the at least one of the fluids is brought to a desired temperature prior to delivery to said catheter (See Figure 1A (16), Column 2 Lines 1-15, Column 4 Lines 25-36).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the temperature and pressure control and heat exchanger taught by Hogard et al. in the in the Bene et al. device since it would improve the health of the dialysate recipient.

Claims 11, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Bene et al. discloses the invention as recited in claims 1, 42 above, however, fails to disclose the second delivery line contains a one-way check valve to prevent retrograde flow.

Bene et al. teaches that it is conventional in the art to utilize the first delivery line contains a three-way check valve (See Figure 1 (15)) to prevent retrograde flow.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the check valve taught by Bene et al. in the first delivery line in the second delivery line since it would prevent retrograde flow in the second delivery line.

Claims 14, 33, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090) in view of Collins et al. (PN 6,303, 036).

Bene et al. discloses the invention as recited in claims 1, 25, 42 however, fails to disclose a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system.

Collins et al. teaches that it is conventional in the art to utilize a monitor to detect the temperature or blood pressure of a patient coupled to said pumping system (See Column 5 Lines 34-37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized detecting the blood pressure of a patient since it would improve the effectiveness of the dialysis machine.

Claims 22, 41, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Bene et al. discloses the second fluid is co-mingled with the first fluid a short distance from a target organ (See Figure 1 (9)).

Bene et al. does not disclose expressly the two fluids are co-mingled no further than twelve inches from a target organ.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to limit the co-mingling distance to twelve inches because Applicant has not disclosed that limiting the co-mingling distance to twelve inches provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the standard distance taught by Bene et al. because it would provide adequate fluid transport.

Therefore, it would have been an obvious matter of design choice to modify Bene et al. to obtain the invention as specified in claims 22, 41, 54.

Claims 24, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bene et al. (PN 5,698,090).

Regarding claims 24, 53 Bene et al. discloses the invention as recited in claims 1, 42 above and further discloses said catheter is inserted into a circulatory vessel (See Figure 1 (9)) remote from a target organ and maneuvered to the target organ, said catheter having a single lumen (See Figure 1 (9)).

Bene et al. discloses the claimed invention except for the multiple lumen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the number of lumen, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis paper Co. v. Bemis Co.,* 193 USPQ 8.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kenley et al. (PN 5,690,821), Burkholder (PN 3,072,064), Rosenqvist et al. (PN 6,440,311), Bene et al. (PN 6,325,774) and Collins (PN 6,161,060) disclose similar fluid pumping systems.

Any inquiry concerning this communication from the Examiner should be directed to Examiner Jaime Corrigan whose telephone number is (571) 272-4858. The Examiner can normally be reached on Monday – Friday from 8:30 a.m. – 6:00 p.m. 2nd Friday off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kevin C. Sirmons, can be reached on (571) 272-4965. The fax number for this group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-3700.

JC

Jaime Corrigan

Jaime Corrigan

Patent Examiner
Art Unit 3767

May 16, 2006

KEVIN SIRMONS
PRIMARY EXAMINER

Kevin C. Sirmons